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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,658	11/29/2006	Luc Terragno	065691-0464	2153

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EXAMINER	
KING, FELICIA C	

ART UNIT	PAPER NUMBER
1789	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,658	TERRAGNO ET AL.	
	Examiner	Art Unit	
	FELICIA C. KING	1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12-20 and 28-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12-20 and 28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/28/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/11 has been entered. Claims 1, 3-10, 12-20, 28-36 are pending. Claim 36 is new.

Claim Objections

1. Claims 34 and 36 are objected to because of the following informalities: claims 34 and 36 are both dependent upon claim 15 and recite the same limitation upon claim 15. The claims are redundant. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1, 3-8, 12, 17, 30, 31, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Applicants' NPL - Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Applicants' NPL- Journal of Applied Microbiology 2003 95, pg 146-154).**

Regarding Claims 1, 3, 6-8, 30 and 31: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter [pg 404, ***Medium***] and where a cross flow filtration system (tangential microfiltration) is used to wash and feed bacteria with fresh medium and to concentrate the bacteria in order to get high density cultivation of bacteria where the concentration is $1x10^{11}$ cfu/ml and where the bacteria are used in yogurt drinks [pgs 404,405 ***Culture***, pg 408].

Hayakawa does not explicitly disclose where the bacteria obtained in the fermenter are adapted and the measurement of those parameters.

Maus discloses where Bifidobacterium are subjected to acidic pH and cold temperature conditions in order to adapt them for their application in ready to consume probiotic products [Abstract; pg. 148].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa and Maus before him or her to adapt the bacteria to tolerate low temperatures and acidic pH levels because these are levels typical of dairy products and doing such would prolong the availability of the beneficial effects of bacteria like the Lactobacilli and Bifidobacteria disclosed in Hayakawa and Maus and other probiotics.

Although Hayakawa does not disclose the amount of a bacterial concentration being greater than 1 $x10^{11}$ it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the growth and filtration parameters in order to achieve a bacterial concentration greater than 1 $x10^{11}$, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Regarding Claim 4: Hayakawa discloses where the medium is maintained throughout propagation at a pH of 6.5 but does not disclose where the pH is between 3 and 6 at the end of propagation. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the pH for the intended application especially where the bacteria are adapted at acidic levels, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Borsch*, 617 F.2d 272.

Regarding Claim 5: Hayakawa discloses where the number of cells available after growing in a fermenter is $1x10^{11}$ cfu/ml (greater than $2x10^{10}$ cfu/ml).

Regarding Claims 12 and 33: Hayakawa discloses where the microfiltration membrane is .14 μm [pg. 404, Bioreactor with membrane module].

Regarding Claim 17: Hayakawa discloses where the bacteria are revived and precultured (where the bacteria were stored at 4°C and were then precultured) [pg. 404, *Microorganisms* and *Culture*].

4. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154), as applied to claim 1 above and in further view of SCK·CEN "Physiological Approach to Monitor Space and Stress Response in Bacteria" 2003.**

Regarding Claim 9: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above and Maus discloses pH and cold stress applied to bacteria. The references do not disclose where the parameter is bacteria size.

SCK·CEN discloses that physiological stresses such as pH can affect the size of bacteria [col. 1, Objectives].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, and SCK·CEN before him or her to modify the method of adaptation as disclosed in Maus to include the adaptation using detection of bacteria shape as discussed in SCK·CEN as it has been disclosed that exposing bacteria to stress can cause a change in the size of the bacteria. Further, the reaction to stress can be an indicator as to whether the bacteria would react favorably under desirable conditions.

5. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al.**

(Journal of Applied Microbiology 2003 95, pg 146-154), as applied to claim 1 above and in further view of McDaniel (US 2004/0175407).

Regarding Claim 10 and 32: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above. Hayakawa does not disclose that the lengths of the bacteria are between 0.1 to 10 μm or 0.5 to 5 μm (claim 32).

McDaniel discloses where species of Lactobacillus have lengths in the range of 1.0 -10 μm, species of Bifidobacterium have lengths in a range of 1.5 - 8.0 μm, species of Streptococcus have lengths in a range of 0.5 – 2.0 μm, species of Lactococcus lengths in the range of 0.5 -1.5 μm [pg 21, Table 3].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, and McDaniel before him or her to include bacteria having lengths of between 0.1 to 10 μm since these are physical characteristics exhibited by the preferred bacteria of the invention and because they are also the same bacteria disclosed in Hayakawa and Maus.

Regarding claim 32, although McDaniel does not disclose Lactobacillus and Bifidobacterium having lengths from 0.5 to 5.0 μm, one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by McDaniel overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. *In re Malagari* 182 USPQ 549,553.

6. Claims 13, 15, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408)

and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above, and in further view of van Reis (US 5,256,294).

Regarding Claims 13: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above. Hayakawa does not disclose where the inlet pressure is between 0 and $3x10^5$ Pa.

van Reis discloses where the tangential microfiltration flow has an inlet pressure of 35 or 50 psi ($2.4\ x10^5$ or $3.4\ x10^5$ Pa) [col.18, lines 51-53].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and van Reis before him or her to modify the filtration method of Hayakawa to include an inlet pressure of $2.4\ x10^5$ or $3.4\ x10^5$ Pa in order to better select out desired species [col. 5, lines 5-15].

Regarding Claims 15 and 34: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above. Hayakawa does not disclose that the transmembrane pressure is between $0.1x10^5$ ($1x10^4$) and $2x10^5$ Pa (claim 15) or between $0.1x10^5$ ($1x10^4$) and $.5\ x10^5$ Pa ($5x10^4$) (claim 34).

van Reis discloses where the transmembrane pressure is 5 and 10 psi ($3.4\ x10^4$ or $6.8\ x10^4$ Pa) [col. 18, lines 54-55].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and van Reis before him or her to modify the filtration method of Hayakawa to include a transmembrane pressure of $3.4\ x10^4$ or $6.8\ x10^4$ Pa in order to better select out desired species and to ensure that the desired bacteria are pushed through the filter [col. 5, lines 5-15].

Regarding claim 34, although van Reis does not disclose the transmembrane pressure being from $0.1x10^5$ ($1x10^4$) and .5 $x10^5$ Pa ($5x10^4$), one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by van Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. *In re Malagari* 182 USPQ 549,553.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154), as applied to claim 1 above and in further view of Carrere et al. (Applicants' NPL - Journal of Membrane Science 2001 vol. 186 219-230).

Regarding Claim 14: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above. Hayakawa does not disclose where the rate of the permeate is between 0.001 and 0.1 $m^3/h/m^2$.

Carrere discloses permeate flux at 42 $l/h/m^2$ (.042 $m^3/h/m^2$) [pg. 228 Table 4].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and Carrere before him or her to modify the filtration method of Hayakawa to include a permeate flux of .042 $m^3/h/m^2$ in order to obtain higher values of concentrated bacteria.

8. Claims 16 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154)as applied to claim 1 above, and in further view of Ebner et al. (US 3,974,068).

Regarding Claims 16 and 35: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not disclose a recirculation rate of 0.5 $m^3/h/m^2$ to 3.0 $m^3/h/m^2$ or .8 $m^3/h/m^2$ to 1.25 $m^3/h/m^2$ (claim 35). However, Ebner discloses recirculation rates at .078 $m^3/h/m^2$ and discloses a starting recirculation rate of .1 $m^3/h/m^2$[col. 8, lines 63-66, col. 9, lines 10-12].

At the time of the invention it would have been obvious to one having ordinary skill in the art having the teachings of Hayakawa, Maus and Carrere before him or her to modify the filtration method of Hayakawa to include recirculation rate in order to increase filter efficiency.

Although, Ebner does not disclose the same recirculation range as disclosed in the instant claim, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the recirculation rate based upon the size and concentration of bacteria and amount of medium used which would influence the rate of recirculation and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

9. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above and in further view of Bensel (US 2,364,049).

Regarding Claims 18 and 19: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not discloses where the liquid concentrate is packaged in flexible and hermetic bags and where the liquid concentrate in the bags are kept at temperatures of -50° C to 4°C. However, Bensel discloses packaging perishable items by sterilizing them and loading into flexible heat sealable bags that are impervious to air and moisture

(hermetic) [pg. 2, 1st col. lines 53-58] and where the bags are kept at temperatures lower than -10°C [pg. 2, 2nd col. lines 38-41].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus and Bensel before him or her to package the liquid concentrate in flexible hermetically sealed, sterile packaging at low temperatures because it would prevent the degradation of the liquid concentrate (maintain the shelf life) and prevent contamination with undesirable pathogenic bacteria or bacteria that has not been adapted for use as probiotics.

10. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) and Bensel (US 2,364,049), as applied to claim 19 above and in further view of Rinfret et al. (US 3,228,838).**

Regarding Claim 20: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not explicitly disclose reheating to a temperature between 25°C and 45°C. However, Rinfret discloses preserving biological substances such as blood, bacteria, yeast, beverages from degradation by freezing and then thawing at 37 °C [col. 1, lines 16-20; col. 7, lines 13-37].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, Bensel, and Rinfret before him or her to thaw the bacteria at 37 °C because it would bring the bacteria to a temperature that is favorable to maintaining their viability [Rinfret, col. 3, lines 16-19].

11. **Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al. (Journal of Fermentation and Bioengineering Vol. 70 No. 6 p 401-408) and**

Maus et al. (Journal of Applied Microbiology 2003 95, pg 146-154) as applied to claim 1 above and in further view of Bengtsson-Riveros et al. (US 2004/0115308).

Regarding Claims 28 and 29: Hayakawa discloses where Lactobacilli are grown in synthetic culture medium in a fermenter as discussed above but does not explicitly disclose where the bacteria are added to a food product at the end of a production line. However, Bengtsson-Riveros discloses where the bacteria can be directly added to the consumable product and stored with the consumable product [pg. 2, para 0024] and further discloses adding probiotics to the consumable product before packaging the product [pg. 3, para 0040].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Hayakawa, Maus, and Bengtsson-Riveros before him or her to include the addition of the bacteria after the food is produced and before packaging in order to further ensure that the bacteria is exposed to temperatures at which the food will be stored, which will further help the bacteria maintain its viability and help maintain the overall shelf stability of the food product.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 6-9, 18, 19, 20, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-10, 12, 15, 16, 19 and 22 of copending Application No. 10/509,507. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed toward adapted liquid bacterial concentrates that are treated by tangential microfiltration; where the bacteria are Lactobacilli, Bifidobacterium, Streptococcus, or Lactococcus; where the parameters are measured by the medium or bacteria; where the bacteria is added at the end of a production line and packaged in flexible hermetically sealed bags and can be reheated after packaging.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. New rejections made above are in light of the addition of new claim 36.

15. Applicants have overcome the 112 2nd rejection of claim 15.

16. The provisional double patenting rejection stands and is not erroneous because the Examiner is permitted to make a provisional double patenting rejection in the case of non-patented conflicting claims.

17. Applicant's arguments filed 3/28/11 have been fully considered but they are not persuasive. As asserted in the previous Remarks, Applicants assert that it would not have been obvious to combine Hayakawa (tangential flow) and Maus (adaptation of bacteria) because other prior art references Reid and Crespo, disclose that further work was needed to determine whether tangential

flow can be applied in processing other bacterial species outside of *Corynebacterium parvum* and because tangential flow causes mechanical stress that impairs cell viability.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

In this case, the prior art used in the rejection (Hayakawa and Maus) clearly show that whatever concerns that were raised in the art by Reid and Crespo have been either overcome in the art or were not relevant to give rise to questions of applicability within the art.

Further, it would have been obvious to one of ordinary skill in the art to combine tangential flow with adapted bacteria since during the process of adapting bacteria; there is a decrease in cell populations [Maus, pg, 150, Results]. There is a need to cultivate and concentrate as many surviving cells as possible. Tangential filtration makes this possible because it provides a culture method that produces bacterial cells in high density [Hayakawa, pg. 404].

Applicants' main arguments now appear to be that the Hayakawa reference does not disclose increasing the concentration of viable cells using tangential microfiltration (cross-flow microfiltration) and merely discloses removing toxic metabolites using tangential microfiltration (cross-flow microfiltration.

The Examiner disagrees. In particular, Hayakawa discloses the method for producing a high density culture of Lactobacilli by using cross flow (tangential filtration) culture methods. Hayakawa

discloses the importance of Lactobacilli as starter bacteria in fermented milk composition and drinking yogurt and that it regulates bowel fermentation. When bacteria are used as starters, it is generally known that the bacteria are viable, i.e. living and able to produce more bacteria in order to ferment the milk and to ferment the milk to the extent that the desirable and known flavor and other organoleptic properties are achieved. The purpose of the study in Hayakawa was to produce Lactobacilli in high density cultures. Because Hayakawa discloses the importance of Lactobacilli as starters in food production, it is clear and would have been obvious to one of ordinary skill that the method of concentrating the bacilli would have resulted in viable bacteria especially since Hayakawa also counts the number of viable cells using methods known in the art [pg 405 Analysis]. Examiner notes that Applicants assert that Hayakawa is not drawn to viable cells because it counts the cell concentration using dry cells. Examiner disagrees because Hayakawa's counting of dry cells is a moot argument especially since in the next sentence Hayakawa discloses counting viable cells using "BSP agar" plate.

Further, it appears that in Hayakawa there is dual removal of toxic metabolites from the medium and an increase in the density of the culture and therefore Hayakawa is still commensurate with the scope of the invention. The Applicants have not provided evidence as to how the claimed invention is not obvious over what is disclosed in Hayakawa. Applicants merely state "the bacteria adapted is concentrated in bacteria by tangential microfiltration to a bacterial concentration...". The concentration of bacteria is accomplished in Hayakawa. Applicants have not provided evidence nor do the claims recite a method that is not obvious over Hayakawa.

The Examiner acknowledges Applicants' submission of a June 2008 thesis presented by Fernanda Streit. In the thesis, Streit states that no work is available about the use of cross-flow microfiltration as a means for concentrating lactic acid bacteria during starter production processes

[pg. 3]. Streit states that the closest prior art is directed towards separating lactic acid bacteria from liquid portions. The Examiner cannot reconcile the disclosure in Streit with what is disclosed by Hayakawa. Hayakawa clearly discloses concentrating lactic acid bacteria using cross flow microfiltration. Streit does not reference Hayakawa and provides no comparison to the method it lays out in contrast to Hayakawa. Examiner notes that the methods used by Streit are very similar to Hayakawa. For example,

18. Further, Applicants appear to be emphasizing the viability of the bacteria *following* tangential filtration. The parameters regarding the term "following" are unclear and further this argument does not pertain to the claims as recited. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the viability of the bacteria *following* tangential filtration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants have not argued that the limitations of the claims were not met by the Hayakawa reference in combination with Maus and other tertiary references therein.

The rejections stand.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Corre et al. Journal of Chem. Tech. Biotechnol 1992 vol. 53, 189-194 disclosing the production of concentrated and viable *Bifidobacterium bifidum* and direct concentration by cross-flow membrane filtration [pg. 193; Part 3.4 and Conclusion].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on 571-272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Humera N. Sheikh/
Supervisory Patent Examiner, Art Unit 1789

/F. K./
Examiner, Art Unit 1789